

DEC - 1 2004

**510(k) Summary of Safety and Effectiveness for the  
Diomed, Inc. EVLT Kit and D15Plus and D30Plus Lasers**

K 041957

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

**1. General Information**

Submitter: Diomed, Inc.  
One Dundee Park, Suites 5 and 6  
P.O. Box 97  
Andover, MA 01810

Contact Person: Maureen O'Connell  
5 Timber Lane  
North Reading, MA 01864  
Telephone: 978-207-1245  
Fax: 978-207-1246

Summary Preparation Date: November 16, 2004

**2. Names**

Device Name: EVLT Kit and D15Plus and D30Plus Lasers

Classification Name: Laser Instrument, Surgical Powered  
Product Code: GEX  
Panel: Dermatology and Plastic Surgery

**3. Predicate Devices**

—  
The EVLT Kit and the D15Plus and D30Plus Lasers are substantially equivalent to the Diomed EVLT Kit and D15Plus and D30Plus Diode Lasers (K023543), the Diomed 810 nm Surgical Lasers and EVLT Procedure Kit (K012398) and the Diomed 15Plus and Diomed 30Plus Lasers (K013499).

**4. Device Description**

The DIOMED 15 Plus is a diode laser capable of delivering up to 119 J/cm<sup>2</sup> of pulsed radiation via a fiber optic handpiece or 0.5-15 W of continuous wave radiation via an optical fiber coupled to the laser aperture. The DIOMED 30 Plus is a diode laser capable of delivering up to 400 J/cm<sup>2</sup> of pulsed radiation via a fiber optic handpiece or 0.5-30 W of continuous wave radiation via an optical fiber coupled to the laser aperture.

An EVLT procedure kit is available which may contains a 400 -1000 micron core, 2.5 meter long bare tip fiber with location markers, a 25-100 cm long, 4- 5 Fr graduated introducer sheath with dilator, a 19 Gauge, 7 cm percutaneous entry needle, and a 0.035" J guide wire.

**5. Indications for Use**

The 810nm Diomed Laser and EVLT Procedure Kit are intended for use in the treatment of superficial vein reflux of the greater saphenous vein associated with varicosities. The Diomed D15 plus and D30 plus and EVLT Kits are indicated for treatment of incompetence and reflux of superficial veins in the lower extremity.

**6. Performance Data**

Clinical data was presented on 213 subjects treated with endovenous laser treatment with the Diomed D15Plus Laser System and EVLT Kit.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Diomed Inc.  
C/o Ms. Maureen O'Connell  
Regulatory Consultant  
5 Timber Lane  
North Reading, Massachusetts 01864

Re: K041957  
Trade/Device Name: EVLT Kit and D15 Plus and D30 Plus Laser Systems  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology  
Regulatory Class: II  
Product Code: GEX  
Dated: October 15, 2004  
Received: October 18, 2004

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

*Miriam C. Provost*

for Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K041957

Device Name: EVLN Kit and D15 Plus and D30 Plus Laser Systems

Indications For Use:

The 810nm Diomed Laser and EVLT Procedure Kit are intended for use in the treatment of superficial vein reflux of the greater saphenous vein associated with varicosities. The Diomed D15 plus and D30 plus and EVLT Kits are indicated for treatment of incompetence and reflux of superficial veins in the lower extremity.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

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